

**Remarks**

The undersigned would like to thank the Examiner for the interview conducted on April 6, 2006. Claims 95, 102, and 106 have been amended to define the PHA film as having a molecular weight greater than 420,000. Support for the amendment is found, for example, on page 7, lines 1-2 and page 19, lines 25-27.

**Rejection Under 35 U.S.C. § 112, first paragraph**

Claims 95-115 and 125-135 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. Applicants respectfully traverse this rejection to the extent it is applied to the claims as amended.

In order to facilitate prosecution and without making any admissions regarding alleged new matter, claims 95, 102, and 106 have been amended to define the PHA film as having a molecular weight greater than 420,000. Support for the amendment is found, for example, on page 7, lines 1-2 and page 19, lines 25-27.

**Previous Anticipation and Obviousness Rejections**

In the final Office Action mailed on November 29, 2005, the Examiner indicated that if the alleged new matter (i.e. greater than 456,000) was deleted from claims 95, 102, and 106, the previous anticipation and obviousness rejections would be reimposed (page 2, Section 3). The obviousness and anticipation rejections were presented in the Office Action mailed on August 2,

2005 (*see* pages 3-5). Claims 95, 102 and 106 have been amended to define the PHA film as having a molecular weight greater than 420,000. Arguments in response to the previous anticipation and obviousness rejections are provided below.

**Previous Rejection Under 35 U.S.C. § 102**

Claims 66, 78-80, 94, 102, 104, 105, and 116 were previously rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,217,803 to McBride (“McBride”) or U.S. Patent No. 5,300,576 to Nemphos (“Nemphos”). Claims 66, 78-80, 83, 89, 94, 102, 104, 105, 116, 123, and 124 were previously rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,753,782 to Hammond *et al.* (“Hammond”). Claims 66-73, 76, 78-89, 92, 94-111, 114, and 116-127 were previously rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,061,743 to Herring *et al.* (“Herring”). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

**The Legal Standard**

For a rejection of claims to be properly founded under 35 U.S.C. § 102, it must be established that a prior art reference discloses each and every element of the claims. *Hybritech Inc. v Monoclonal Antibodies Inc.*, 231 U.S.P.Q. 81 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); *Scripps Clinic & Research Found v. Genentech Inc.*, 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991). The Federal Circuit held in *Scripps*, 18 U.S.P.Q.2d at 1010:

Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . There must be no difference between the

claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. (Emphasis added)

A reference that fails to disclose even one limitation will not be found to anticipate, even if the missing limitation could be discoverable through further experimentation. As the Federal Circuit held in *Scripps*, Id.:

[A] finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill in the gaps in the reference.

For a prior art reference to anticipate a claim, it must enable a person skilled in the art to practice the invention. The Federal Circuit held that "a §102(b) reference must sufficiently describe the claimed invention to have placed the public in possession of it. . . [E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling." *Paperless Accounting Inc v Bay Area Rapid Transit Sys.*, 231 U.S.P.Q. 649, 653 (Fed. Cir. 1986).

#### Analysis

Claims 66-73, 76, 78-89, 94, and 116-124 were canceled in the Amendment and Response filed on November 2, 2005.

*McBride*

McBride describes biodegradable films that comprise a blend of an interpenetrated network of destructureized starch with ethylene/acrylic acid copolymers or ethylene/vinyl alcohol copolymers, and an aliphatic polyester such as polycaprolactone. In a preferred embodiment, the aliphatic polyester is polycaprolactone with an initial molecular weight of about 80,000 grams/mole (col. 5, lines 37-39). The claims, as pending, are not directed to interpenetrated networks. McBride does not disclose or suggest a blown or cast free-standing film comprising a polyhydroxyalkanoate (PHA), wherein the PHA has a Mw greater than 420,000 and wherein the film is made from a pellet composition comprising the PHA and a thermal stabilizer nor methods of making thereof. In fact, McBride is silent regarding the molecular weight of the PHA in the film. McBride does not disclose or suggest a method of making a blown or cast film as defined in claim 102, wherein the PHA in the pellet has a molecular weight greater than 470,000 (claim 106). Therefore, the claims, as amended, are novel over McBride.

*Nemphos*

Nemphos describes polymer blends having a  $T_g$  of not less than 62°C, comprising a polyhydroxyalkanoate having a molecular weight greater than 40,000 and one or more polymers having a  $T_g$  from 75°C to 200°C (col. 2, lines 28-50). Suitable PHAs are described at col. 3, lines 3-16). Nemphos discloses that pellets of the polymer blends can be injection molded or thermoformed to produce various articles such as sheets and containers. Nemphos, however, does not disclose a method of producing **blown or cast free-standing films** comprising melting

a composition comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 420,000. In fact, Nemphos does not disclose or suggest PHA **films** nor methods of making thereof. Therefore, the claims, as amended, are novel over Nemphos.

***Hammond***

Hammond describes polyester compositions comprising a biodegradable polyester and a plasticizing quantity of at least one plasticizer selected from the group consisting of high boiling esters of polybasic acids, phosphoric acid derivatives, phosphorous acid derivatives, phosphonic acid derivatives, substituted fatty acids, high boiling glycols, polyglycols, polyoxyalkylenes, and glycerol (abstract). Hammond does not disclose or suggest **blown or cast free-standing films** comprising melting a composition comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a **molecular weight greater than 420,000** and wherein the film is made from a pellet composition comprising the PHA and a thermal stabilizer nor methods of making thereof. Hammond describes extruding compositions containing PHBV and a nucleant to form a single lace, which is dried and cut into granules. The granules are injection molded into dumbbell shaped tensile bars (Examples 1-3). There is no disclosure in Hammond of extruding a PHA and a thermal stabilizer to form pellets and then extruding the pellets to form a film, wherein the film has a molecular weight greater than 420,000. Therefore, the claims, as amended, are novel over Hammond.

*Herring*

Herring discloses PHA compositions comprising a PHA and a nucleating agent composed of a combination of an organophosphonic or organophosphoric acid or ester with an oxide, hydroxide, or carboxylate of a metal of Group I to V. Examples 1-4 describe extruding HB polymers containing varying amounts of HV monomer. Example 5 describes injection molding a formulation containing HB polymer containing 17% HV monomer. Herring does not disclose a **blown or cast free-standing film** comprising a PHA and a thermal stabilizer, **wherein the PHA in the film has a molecular weight greater than 420,000**. Herring does not disclose blown or cast films having a draw ratio from 2 to 7, an elongation at break of greater than 65%, or a tensile strength greater than 50 Mpa (claims 97, 98, and 100, respectively). Herring discloses tensile strength (Young's modulus) data for molded tensile bars (Table 6), but nor for blown or cast free-standing films. Therefore, the claims, as amended, are novel over Herring.

**Previous Rejection Under 35 U.S.C. § 103**

Claims 66-73, 76, 78-89, 92, 94-111, 114, and 116-127 were previously rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,061,743 to Herring *et al.* ("Herring"), in view of U.S. Patent No. 5,502,273 to Bright *et al.* ("Bright") or U.S. Patent No. 5,753,782 to Hammond *et al.* ("Hammond") further in view of McBride or Nemphos. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The Legal Standard

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

"There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet*, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however without a motivation to combine, a rejection based on a prima facie case of obvious was held improper.). The level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 U.S.P.Q.2d 1161 (Fed. Cir. 1999).

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580

(CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

**Analysis**

Claims 66-73, 76, 78-89, 94, and 116-124 were canceled in the Amendment and Response filed on November 2, 2005.

***Herring***

As discussed above, Herring does not disclose or suggest a blown or cast free-standing film comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 456,000 nor methods of making thereof. Herring is concerned with the use of nucleants to increase the rate of crystallization. Herring does not disclose or suggest the use of a thermal stabilizer to inhibit the thermal degradation of PHA compositions during film formation.

***Bright***

Bright describes a plant having a recombinant genome which contains or more of the genes specifying enzymes critical to the polyhydroxyalkanoate biosynthetic pathway, which produces polyhydroxyalkanoate polymer. Bright does not disclose or suggest a blown or cast free-standing film comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 456,000 nor methods of making thereof.

***Hammond***

As discussed above, Hammond does not disclose or suggest a blown or cast free-standing film comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 420,000 nor methods of making thereof.

***McBride***

As discussed above, McBride does not disclose or suggest a blown or cast free-standing film comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 420,000 nor methods of making thereof.

***Nemphos***

As discussed above, Nemphos does not disclose a blown or cast free-standing film comprising a PHA and a thermal stabilizer, wherein the PHA in the film has a molecular weight greater than 420,000 nor methods of making thereof.

***Herring In View of Bright or Hammond Further In View of McBride or Nemphos***

One of ordinary skill in the art would not be motivated to modify the references as required to produce the claimed compositions and methods. Additionally, if one did combine the references, one would not arrive at the claimed compositions and methods. None of the references cited by the Examiner disclose or suggest a blown or cast free-standing film comprising a polyhydroxyalkanoate (PHA), wherein the PHA has a Mw greater than 420,000 and wherein the film is made from a pellet composition comprising the PHA and a thermal

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stabilizer. As noted in the specification, extruded PHAs having molecular weights greater than about 420,000 provide a desirable combination of melt strength during initial film formation and subsequent drawability sufficient for use in stable blown film and cast film processes (page 19, lines 25-27). Further, applicants disclose that higher molecular weight PHA films (i.e. greater than 420,000) could be produced without encountering processing difficulties due to unacceptably high viscosities. However, one of ordinary skill in the art would not have expected PHA films having a molecular weight greater than 420,000 to exhibit the physical properties disclosed by the applicants. The references cited by the Examiner do not disclose or suggest that higher molecular weight PHA films would exhibit the desirable combination of melt strength during initial film formation and subsequent drawability for use in stable blown and cast film processes described by the applicants. Therefore, the claims, as amended, are not obvious over Herring in view of Bright or Hammond further in view of McBride or Nemphos.

Allowance of claims 95-115 and 125-135, as amended, is respectfully solicited.

Respectfully submitted,

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